



FLORIDA SOCIETY OF CLINICAL ONCOLOGY FAX BLAST – October 11, 2007

SPECIAL ANNOUNCEMENTS: Robert Cassell, MD, President

Cephalon Oncology – First 2008 Corporate FLASCO Member:

FLASCO issues a very special thanks to **Cephalon Oncology** for becoming our first 2008 Corporate Member! The **Platinum** Membership is greatly appreciated

Dr. Greg Bruce

We have just learned that Dr. Greg Bruce, long-time FLASCO Member, has been diagnosed with head and neck cancer and is being treated at MD Anderson Cancer Center in Houston. You may send cards and messages to Dr. Bruce at: The University of Texas, M. D. Anderson Cancer Center, 1515 Holcombe Blvd, Houston, TX 77030 1-800-392-1611 (USA) / 1-713-792-6161 - or you can access the MD Anderson message center to have an email delivered directly to Dr. Bruce at <https://www2.mdanderson.org/sapp/contact/message.cfm>. You may also send notes and cards to the home address: Dr. and Mrs. W. Greg Bruce, 508 Bunkers Cove Road Panama City, FL 32401

CLINICAL PRACTICE COMMITTEE UPDATES: Thomas Gaddis, MD, Chm.

Aranesp ASP Pricing:

FCSO (Florida Medicare) was asked to research the issue concerning Aranesp ASP pricing. Unfortunately, a mass adjustment will not be performed on these services. However, a telephone or written appeal may be submitted. If requesting a telephone appeal, you will be provided with a confirmation number that will then allow you to fax in additional patients. The form is attached to this fax blast for your convenience and you can also locate the form on FCSO website under: Medicare Part B - Form titled: Telephone Clerical Re Opening. Up to **10 forms** may be submitted per day. **YOU MUST OBTAIN A CONFIRMATION NUMBER FIRST PRIOR TO SUBMITTING FORMS**

McKesson Expands Specialty Pharmaceutical Business with Agreement to Purchase OTN

McKesson Corporation (NYSE:MCK) announced that it has signed a definitive agreement to purchase Oncology Therapeutics Network (OTN), a U.S. distributor of specialty pharmaceuticals. Sales of specialty drugs are increasing rapidly, especially oncology drugs, and OTN is one of the nation's largest distributors of specialty drug products, serving the needs of more than 3,500 oncologists, 1,500 rheumatologists and other providers

DRUG UPDATES

Survival Data In FDA Approval For ERBITUX® (Cetuximab) Supports Use As A Single Agent In Patients With Advanced Colorectal Cancer

ImClone Systems Incorporated and Bristol-Myers Squibb Company announced on Oct. 2, 2007, that the FDA has approved an update to the Erbitux (cetuximab) product labeling to include overall survival data as a single agent in epidermal growth factor inhibitor (EGFR)-expressing metastatic colorectal cancer patients after failure of both irinotecan- and oxaliplatin-based regimens. The approval of the supplemental biologics license application is based on prolonged overall survival from a large, randomized, multicenter Phase III trial comparing Erbitux plus best supportive care (BSC) to BSC alone in 572 EGFR-expressing colorectal cancer patients after failure of irinotecan- and oxaliplatin-based regimens. BSC included all approved palliative therapies designed to alleviate pain and treat other effects caused by the colorectal cancer in this patient population.

APP Receives Tentative FDA Approval for Irinotecan Hydrochloride Injection, 20 mg/mL Packaged in 2 mL and 5 mL Single-Use Vials

Abraxis Pharmaceutical Products (APP), the hospital-based business of Abraxis BioScience, Inc. (NASDAQ:ABBI), announced the tentative approval from U.S. Food and Drug Administration (FDA) to market Irinotecan Hydrochloride Injection, 20 mg/mL, 2 mL, and 5 mL, the generic equivalent of Camptosar(R) Injection manufactured by Pfizer Inc. APP will package this product in 40 mg/2mL and 100 mg/5mL single-use vials.

As one of the only companies to receive a tentative approval, APP is in the process of securing contracts and expects to commence marketing of this product upon patent expiry in February 2008.

PROGRAM PLANNING COMMITTEE: Gerardo Colon-Otero, MD, Chm.

Please plan to attend the November 9-10, 2007, FLASCO Fall Meeting at the Rosen Shingle Creek Hotel near Orlando. We really **need members to attend this meeting** and show the strength of FLASCO to the ASCO President, Dr. Nancy Davidson, who will speak at this meeting.

ASCO UPDATES:

Representatives Introduce Legislation on ESA Coverage

Members of Congress continue to weigh in with the Centers for Medicare & Medicaid Services (CMS) on coverage of ESAs. On September 27, Reps. Anna Eshoo (D-CA) and Mike Rogers (R-MI) introduced [H.J.RES.54](#), a Joint Resolution disapproving CMS's National Coverage Decision (NCD) on the use of ESAs in cancer and related neoplastic conditions. If passed by both the House and Senate and signed by the President, this Joint Resolution would have the force of law and would prohibit CMS from implementing the coverage change.

In addition, Rep. Stephen Cohen (D-TN) also introduced a resolution, [H.RES.681](#), urging CMS to reconsider its coverage decision on ESAs and consult with members of the oncology community to make appropriate revisions to its policy. This resolution is a companion bill to the Senate resolution passed September 4.

ASCO applauds Reps. Eshoo, Rogers, and Cohen for their action and their continued commitment to cancer care. Please call your Representative, tell him or her the effect this policy change is having on your practice and your patients, and urge him or her to co-sponsor these important pieces of legislation.

President Signs Legislation to Reauthorize Prescription Drug User Fee Act

On September 27, the President signed the Food and Drug Administration (FDA) Revitalization Act of 2007 (HR 3580), expanding FDA oversight of prescription drug safety and reauthorizing the Prescription Drug User Fee Act, which was set to expire September 30.

The following provisions of the bill are likely to affect the cancer community:

- **Drug Safety:** The law gives FDA authority to require pharmaceutical companies to conduct post-marketing studies to assess a known serious risk and signals of a serious risk, or identify an unexpected serious risk. The bill empowers FDA to require companies to submit "Risk Evaluation and Mitigation Strategies" (REMS) and to impose fines on companies for failure to follow post-market safety procedures.

The legislation also provides mechanisms for FDA to conduct risk identification and analysis of marketed drugs. FDA would be required to establish public, academic and private partnerships that would allow for the active mining of electronic health databases for the purposes of post-market safety surveillance. Currently the U.S. Drug Safety System relies on the voluntary reporting of health practitioners and patients to assess drug safety signals.

- **Conflict of Interest Waivers:** FDA will face limits on the number of waivers it will be able to issue for members of its advisory committees. The compromise provision requires the agency to calculate the combined number of waivers granted this year and decrease that number by 5 percent per year between 2008 and 2012. Additionally, disclosure of waivers would have to be made public at least 15 days before an advisory committee meeting.

- **Clinical Trials Database Becomes Mandatory:** Sponsors of all clinical trials involving drugs, biologics and devices will be required to provide information to a clinical trials registry. Sponsors who fail to comply with this requirement would face monetary penalties. The bill also obligates HHS to develop rules for potential inclusion of clinical trial results in a separate database.

Other provisions include establishment of user fees for the review of Direct-to-Consumer advertisements and the authority to require a preview of pharmaceutical TV ads. For more information, contact ASCO's Cancer Policy & Clinical Affairs Department at 703-299-1050 or publicpolicy@asco.org

FCSO UPDATES:

Part A:

Temporary Holding of Inpatient and Long-Term Care Hospital Claims

Last Modified: 10/8/2007

Hospital claims processed under the inpatient prospective payment system and the long-term care hospital prospective payment system, with discharge dates on or after October 1, 2007, are temporarily on hold until October 15, 2007. [JSM 07548]

Temporary Holding of Skilled Nursing Facility Claims

Last Modified: 10/8/2007

Skilled nursing facility (SNF) claims with discharge dates on or after October 1, 2007, are temporarily on hold until the successful implementation of the updated 2008 SNF prospective payment system (PPS) PRICER. [JSM 07547]

MLM MATTERS

MLM SEO736 -Tamper Resistant Prescription Pads for Outpatient Drugs

Due to the "Extenders Law", which was signed on September 29, 2007, the effective date for use of Tamper Resistant Prescription Pads has been extended from October 1, 2007, to April 1, 2008.

MLN Matters Number: MM5677 - Magnetic Resonance Imaging (MRI) Procedures - Implementation Date: October 22, 2007

Effective January 1, 2007, separate payment is made for the contrast media used in various imaging procedures. The cost of the contrast media is no longer included in the practice expense (PE) relative values units (RVUs) for the procedures

In addition to the Current Procedural Terminology (CPT) code representing the imaging procedure, the appropriate Healthcare Common Procedure Coding System (HCPCS) "Q" code (Q9945-Q9954; Q9958-Q9964) can be separately billed and paid for the contrast medium utilized in performing the service

MM5741 – Correction to Revised HCPCS Codes Relating to Immune Globulin (this CR rescinds and fully replaces CR 5635)

FDA UPDATES:

FDA to Increase Number, Variety of Generic Drugs Under New Program

On Oct. 4, the Food and Drug Administration (FDA) outlined a new program, the Generic Initiative for Value and Efficiency (GIVE), aimed at increasing the number and variety of generic drug products available to consumers and health care providers. As reported in the Oct. 5 *BNA Health Care Daily*, GIVE will help FDA modernize and streamline its generic drug approval process. As part of the GIVE efforts, FDA is revising the review order for certain drug applications. For example, first generic products for which there are no blocking patents or exclusivity protections will be identified at the time of submission for expedited review. This will mean that these products, for which there currently are no generic products on the market, may reach the consumer much faster.

FDA now has about 215 full-time staff working on the review of generic drug applications. Under GIVE, FDA will hire and train new generic drug reviewers and focus on enhanced use of electronic programs for handling drug submissions and internal documents. When possible, resources from other FDA departments will be engaged in the effort. FDA also will increase its communications with generic drug manufacturers and provide training on proper application submission to the industry in meetings and webcasts.

CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2007)

FLASCO Members extends a big thanks to all of our 2007 Corporate Members/Sponsors

PLATINUM

Astra Zeneca
Genentech
Oncology Supply/ION
Sanofi-Aventis
Bristol-Myers Squibb
Eli Lilly
Bayer/Onyx
Ortho Biotech
Abraxis Oncology

GOLD

Cephalon Oncology
Pharmion Corporation
OSI Pharmaceuticals
GlaxoSmithKline
Roche
Pfizer
Amgen

SILVER

Genomic Health, Inc.
Talecris Biotherapeutics
Millennium
Celgene
Novartis

BRONZE

Oncology Pharmaceutical Services

FLASCO EVENTS:

November 9-10, 2007 – FLASCO Fall Meeting – Rosen Shingle Creek – Orlando

March 7-8, 2008 – FLASCO Spring Meeting – Tampa Airport Marriott Hotel

November 7-8, 2008 – FLASCO Fall Meeting – Location TBD

OTHER EVENTS:

The Florida Association of Pediatric Tumor Programs will hold its 30th Anniversary Annual Seminar at the Hyatt Regency Grand Cypress in Orlando from November 15-17, 2007. To register please visit the following Web Site: www.faptp.org

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